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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,888	06/29/2001	Tom A. Grigliatti	4810-59380	3346

7590 04/20/2004

KLARQUIST SPARKMAN CAMPBELL LEIGH & WHINSTON, LLP  
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Portland, OR 97204

EXAMINER

VOGEL, NANCY S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/896,888

Applicant(s)

GRIGLIATTI ET AL.

Examiner

Nancy T. Vogel

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17,23 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-17,23 and 27-29 is/are rejected.
- 7) ☐ Claim(s) 2 and 3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8/5/03 & 12/8/03
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Office action is in response to Applicant's response filed 1/29/04.

Claims 1-17, 23, and 27-29 are pending in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Arguments***

The rejection of claims 1, 4-17, 23 and 27-29 under 35 USC 112, first paragraph, as failing to comply with the written description requirement has been maintained for the reasons set forth below.

The rejection of claims 27-29 under 35 USC 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of applicant's arguments

### ***Claim Rejections - 35 USC § 112***

Claims 1, 4-17, 23 and 27-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for the reasons made of record in the previous Office action, mailed 7/29/03.

Applicants have argued that the specification describes that the shuttle vectors of the present invention can be adapted for use with a variety of antibiotic selection schemes. While it is agreed that the specification makes this statement, it is maintained that the specification has not described other resistance marker genes encoding proteins which may function in insect and prokaryotic cells. It is noted that the specification contains statements regarding the unpredictability of the use of selection markers, which can include amplification and subsequent instability (pages 25 and 27 of the specification), and discloses that only the disclosed zeomycin marker avoids such undesired properties. Therefore, the rejection is maintained.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

4/19/04

  
TERRY MCKELVEY  
PRIMARY EXAMINER



UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,888	06/29/2001	Tom A. Grigliani	4810-59380	3346

7590 07/29/2003

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EXAMINER

VOGEL, NANCY S

ART UNIT	PAPER NUMBER
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1636

9

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



# Office Action Summary

Application No.

09/896,888

Applicant(s)

GRIGLIATTI ET AL

Examiner

Nancy T. Vogel

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17, 23 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17, 23 and 27-29 is/are rejected.
- 7) ☒ Claim(s) 2, 3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☒ None of:  
1) ☒ Certified copies of the priority documents have been received.  
2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Office action is in response to the Preliminary amendment filed by applicants on 4/4/02.

Claims 1-17, 23, and 27-29 are pending in the case.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-17, 23, and 27-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is based on the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112 first paragraph "Written Description" published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). The claims are drawn to shuttle vectors wherein a selectable marker coding sequence is present, and said selectable marker confers a selectable phenotype on insect and bacterial cells transformed with the shuttle vector. The disclosure is not deemed to be descriptive of



the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all the encompassed vectors based on the teachings of the specification. The vectors described in the specification are limited to those containing the zeomycin resistance gene for conferring a selectable phenotype in both prokaryotic and insect cells. While the specification provides some general information on the use of antibiotic resistance genes in insect cell vectors, there is no structure-function analysis of the disclosed zeomycin resistance conferring protein to provide guidance on the selection of other resistance marker genes encoding proteins which may function in insect and prokaryotic cells. Therefore, the specification does not describe the claimed insect-prokaryotic shuttle vectors containing a selectable marker conferring a selectable phenotype in such full, clear, concise and exact terms so as to indicate that Applicant had possession of the claimed shuttle vectors at the time of filing the present application. Thus, the written description requirement has not been satisfied.

Claims 27-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is based on the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112 first paragraph "Written Description" published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). Claims 27-29 are drawn to shuttle vectors containing an insect promoter comprising : an IE2B element having at least 95% sequence identity to SEQ ID NO: 10 (claim 27), a sequence with at least 95% sequence identity to SEQ ID NO:1 from bp 351-527 (claim 28), or a sequence with at least 95% sequence identity to SEQ ID NO 1 (claim 29) wherein the insect promoter is a functional promoter. These claims are genus claims in terms of encompassing numerous variants which have 95% homology to a recited sequence, which remain functional as a promoter. The specification teaches shuttle vectors using an insect promoter having exact homology to the above recited sequences. The disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all the encompassed promoters based on the teachings of the specification. The specification does not provide any structure-function analysis of the disclosed promoter sequences analyzing which alterations may result in functional promoters. Therefore, the specification does not describe the claimed insect-prokaryotic shuttle vectors containing an insect promoter having 95% homology to the recited sequences in such full, clear, concise and exact terms so as to indicate that Applicant had possession of the claimed shuttle vectors at the time of filing the present application. Thus, the written description requirement has not been satisfied.



**Conclusion**

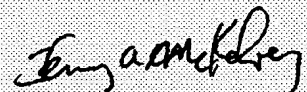
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (703) 308-4548. The examiner can normally be reached on 7:30 - 4:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

\*\*\*

July 24, 2003

  
TERRY MICKELVEY  
PRIMARY EXAMINER

*Response to claims*

#### **REMARKS**

In the Office Action dated July 29, 2003, claims 1-17, 23 and 27-29 are pending and under consideration. Claims 1, 4-17, 23 and 27-29 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to satisfy the written description requirement. Claims 27-29 are further rejected separately under 35 U.S.C. §112, first paragraph, as failing to satisfy the written description requirement.

This Response addresses each of the Examiner's rejections. Applicants therefore respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

Regarding the rejection of claims 1, 4-17, 23 and 27-29 as allegedly failing to satisfy the written description requirement, it is observed that the claims are drawn to shuttle vectors wherein a selectable marker coding sequence is present, and the selectable marker confers a selectable phenotype on insect and bacterial cells transformed with the shuttle vector.

The Examiner contends that the disclosure is not descriptive of the complete structure of a representative number of species encompassed by the claims, allegedly because those skilled in the art cannot envision all the vectors encompassed by the claims based on the teachings of the specification. Specifically, the Examiner alleges that the vectors adequately described in the specification are limited to those containing the zeomycin resistance gene, which confers a selectable phenotype in both prokaryotic and insect cells. The Examiner also alleges that there is no structure-function analysis in the specification of the disclosed zeomycin resistance conferring protein, which would provide guidance on the selection of other resistance marker genes which may function in both insect and prokaryotic cells. Therefore, the Examiner concludes that the specification does not describe the claimed insect-



prokaryotic shuttle vectors in such terms so as to convey to those skilled in the art that Applicants had possession of the claimed shuttle vectors at the time of filing the present application.

In response, Applicants respectfully submit that a shuttle vector containing a selectable marker, which confers resistance to a bleomycin/phleomycin-type of antibiotic, is merely a preferred embodiment of the present application. Applicants should not be required to limit the claims to this preferred embodiment. Applicants respectfully submit that the specification describes that the shuttle vectors of the present invention can be adapted for use with a variety of antibiotic selection schemes. See page 67, lines 20-21, for example. The specification also illustrates how to make a shuttle vector containing a selectable marker suitable for selection in both insect cells and prokaryotic cells (see e.g., pages 23 and 27), and how to determine the genomic stability of the selection marker gene in transformed insect cells (see, e.g., pages 25-27). Based on the present teaching, those skilled in the art would understand that Applicants had possession of the shuttle vectors as presently claimed at the time of filing of the present application. As such, it is respectfully submitted that the claimed shuttle vectors are adequately described in the specification in compliance with the written description requirement of 35 U.S.C. §112, first paragraph. Withdrawal of the rejection is therefore respectfully requested.

Claims 27-29 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement.

Claims 27-29 are drawn to shuttle vectors containing an insect promoter comprising an IE2B element having at least 95% sequence identity to SEQ ID NO: 10 (claim 27), a sequence with at least 95% sequence identity to SEQ ID NO: 1 from base pair 351-527 (claim



28), or a sequence with at least 95% sequence identity to SEQ ID NO:1 (claim 29) wherein the insect promoter is a functional promoter.

The Examiner contends that claims 27-29 are genus claims that encompass numerous variants having 95% identity to a recited sequence while remaining functional as a promoter. The Examiner states that, while the specification teaches shuttle vectors using an insect promoter having exact identity to the recited sequences, the specification does not adequately describe the complete structure of a representative number of species encompassed by the claims. Furthermore, the Examiner contends that the specification does not provide any structure-function analysis of promoter sequences with respect to the alterations that can be made without affecting the function of the promoters.

In response, Applicants respectfully submit that the promoters in the claimed shuttle vectors are adequately described in the specification, both structurally and functionally. In the first instance, the recitation "95% identity" to a specific sequence adequately describe the structure of the promoters. In addition, the specification illustrates how to determine the functionality, host range and efficiency of a promoter at pages 18-21, for example. As such, it is respectfully submitted that the shuttle vectors containing a promoter, as presently claimed, are adequately described in the specification in compliance with the written description requirement of 35 U.S.C. §112, first paragraph. Withdrawal of the rejection is therefore respectfully requested.

Claims 2-3 are objected to apparently because claim 1, which claims 2-3 depend upon, is rejected. It is believed that claims 2-3, if rewritten to incorporate all the delineations of claim 1, would be allowable.

In view of the foregoing amendments and remarks, it is firmly believed that the

subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



Frank S. DiGiglio  
Registration No. 31,346

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XZ:ab/lf

Enc.: Revocation of Prior Power and Appointment of New Power.



### **IN THE CLAIMS:**

1. (Previously presented) A shuttle vector for transforming insect cells and prokaryotic cells, comprising:
  - a) a prokaryotic origin of replication;
  - b) a promoter region comprising an insect promoter and a prokaryotic promoter sequence; and
  - c) a selectable marker coding sequence operably linked to the promoter region, so that the selectable marker is under the transcriptional control of the insect promoter in insect cells and the prokaryotic promoter sequence in prokaryotic cells, wherein the selectable marker is thereby capable of expression in both prokaryotic and insect cells to confer a selectable phenotype on cells transformed with the shuttle vector.
2. (Previously presented) The shuttle vector of claim 1, wherein the selectable marker is capable of conferring resistance to a bleomycin/phleomycin-type antibiotic.
3. (Previously presented) The shuttle vector of claim 2, wherein the bleomycin/phleomycin-type antibiotic is Zeocin.
4. (Original) The shuttle vector of claim 1, further comprising an insertion site for heterologous DNA.
5. (Original) The shuttle of claim 4, wherein the insertion site for heterologous DNA is under the transcriptional control of a second insect promoter.
6. (Original) The shuttle vector of claim 5, further comprising a heterologous DNA sequence inserted at the insertion site and under the transcriptional control of the second insect promoter.
7. (Previously presented) The shuttle vector of claim 1, wherein the insect promoter is an immediate early baculovirus promoter.

8. (Previously presented) The shuttle vector of claims 7, wherein the insect promoter comprises an IE2B element having a sequence ACAGGACGC (SEQ ID NO: 10).
9. (Previously presented) The shuttle vector of claim 8, wherein the insect promoter comprises a sequence as shown in SEQ ID NO: 1 from bp 351 to bp 527.
10. (Previously presented) The shuttle vector of claim 9, wherein the insect promoter comprises a sequence as shown in SEQ ID NO: 1.
11. (Previously presented) The shuttle vector of claim 1 further comprising DNA transposable elements.
12. (Previously presented) The shuttle vector of claim 11, wherein the selectable marker coding is between the transposable elements.
13. (Previously presented) The shuttle vector of claim 12, further comprising an insertion site for heterologous DNA between the transposable elements.
14. (Original) The shuttle vector of claim 13, further comprising a heterologous DNA sequence inserted at the insertion site and under the transcriptional control of a second insect promoter.
15. (Previously presented) The shuttle vector of claim 11, further comprising an inducible transposase gene between the transposable elements.
16. (Original) Insect cells transformed with the shuttle vector of claim 1.
17. (Original) Insect cells transformed with the shuttle vector of claim 11.



18-22. (Canceled)

23. (Previously presented) Recombinant insect cells transformed with the shuttle vector of claim 1, expressing a heterologous insect ion transport peptide hormone.

24-26. (Canceled)

27. (Previously presented) The shuttle vector of claims 7, wherein the insect promoter comprises an IE2B element having at least 95% sequence identity to ACAGGACGC (SEQ ID NO: 10), and wherein the insect promoter is a functional promoter.

28. (Currently amended) The shuttle vector of claim 8, wherein the insect promoter comprises a sequence having at least 95% sequence identity to SEQ ID NO: 1 from bp 351 to bp 527, and wherein the insect promoter is a functional promoter.

29. (Currently amended) The shuttle vector of claim 9, wherein the insect promoter comprises a sequence having at least 95% sequence identity to SEQ ID NO: 1, and wherein the insect promoter is a functional promoter.